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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/855,458	05/15/2001	Patrick Denis Lincoln	SRI/4361	9224

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EXAMINER

SMITH, CAROLYN L

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 09/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/855,458

Applicant(s)

LINCOLN ET AL.

Examiner

Carolyn L. Smith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 June 2005 and 28 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-22, 27, 30, 32, 33, 96-98, 100 and 102-107 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-22, 27, 30, 32, 33, 96-98, 100 and 102-107 is/are rejected.
- 7) ☒ Claim(s) 96 and 105 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission, filed 6/7/05, has been entered.

Amended claims 18, 96, 105, and 106 and cancelled claims 1-17, 23-26, 28-29, 31, 34-95, 99, 101, and 108-125, filed 6/7/05, are acknowledged.

Claims herein under examination are 18-22, 27, 30, 32-33, 96-98, 100, and 102-107.

Claim Objections

Claims 96 and 105 are objected to because of the following informality: Claims 96 and 105 are missing a comma after "initial hypothetical state" on lines 10 and 9, respectively. Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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Claims 18-22, 27, 30, and 32-33 are directed to an article comprising machine-readable media having encoded thereon a model that contains nonfunctional descriptive material that is a compilation or mere arrangement of data (see MPEP 2106(IV)(B)(I)).

This section of the MPEP states:

When nonfunctional descriptive material is recorded on some computer-readable medium, it is not statutory since no requisite functionality is present to satisfy the practical application requirement. Merely claiming nonfunctional descriptive material stored in a computer-readable medium does not make it statutory.

If the "acts" of a claimed process manipulate only numbers, abstract concepts or ideas, or signals representing any of the foregoing, the acts are not being applied to appropriate subject matter. *Schrader*, 22 F.3d at 294-95, 30 USPQ2d at 1458-59. Thus, a process consisting solely of mathematical operations, i.e., converting one set of numbers into another set of numbers, does not manipulate appropriate subject matter and thus cannot constitute a statutory process.

Where certain types of descriptive material, such as music, literature, art, photographs and mere arrangements or compilations of facts or data, are merely stored so as to be read or outputted by a computer without creating any functional interrelationship, either as part of the stored data or as part of the computing processes performed by the computer, then such descriptive material alone does not impart functionality either to the data as so structured, or to the computer.

Therefore, these claims are considered to be nonstatutory subject matter.

Claims 18-22, 27, 30, and 32-33 are directed to machine-readable media comprising a model. These claims do not recite any structural limitations, and may actually be directed to paper upon which the model is typed. As many types of media, including paper, can be "scanned" or read by a computer, mere recitation of a "machine-readable medium" does not limit the claimed product to any particular form, structure, or composition. Applicant is reminded that recorded material, such as songs, books, etc. are not patentable subject matter under 35 USC 101, but may be protected under copyright. MPEP 2106.IV.A.2(a) states:

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“The mere fact that a hardware element is recited in a claim does not necessarily limit the claim to a specific machine or manufacture.” See also *In re Iwahashi*, 888 F.2d 1370, 1374-75, 12 USPQ 2d 1908, 1911-12 (Fed. Cir. 1989), recited with approval in *Alappat*, 33 F.3d at 1544 n.24, 31 USPQ2d at 1558.

It is noted that instant claims 96-98, 100, and 102-107 are considered to be statutory subject matter because these claims are directed to machine-readable media having encoded thereon software configured to cause a processor to perform steps, which demonstrates a functional interrelationship between the data structure and the processor.

Claims 18-22, 27, 30, 32-33, 96-98, 100, and 102-107 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

Claims 18-22, 27, 30, 32-33, 96-98, 100, and 102-107 are directed to an article comprising machine-readable media having an encoded model of a biological system.

It is not clear what one would use the model or program for. It is not clear what is the “practical” result of the encoded software. The “usefulness” of a model of a biological system is not apparent.

The instant invention involves a model of a biological system that undergoes substitutions of symbols representing biological elements. A model of a biological system is generally useful, but one of skill in the art would have to know something particular about the model, such as tissue type, disease represented, or organism involved, in order for the utility to be specific. The specification on pages 26-27 states that the model may be used for generating testable hypotheses that is not a specific utility because it is generally applicable to models in

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general. As stated above, the claims and specification fail to state what specific hypothesis generation might be tested. The specification on pages 26-27 states that the model may be used for diagnostics. The specification on page 28 states that the models could be used to predict disorders characterized by changes in cell proliferation, cell differentiation, cell adhesion, hormone levels, and so forth which are generic in nature. The specification on page 28 states the methods can be used to identify drug targets. However, this identification is a generic utility as there is no mention as to what type of drug, tissue, organism, or disorder is being tested. The specification on pages 26 and 28 state that the models can be used for designing artificial regulatory circuits which is a generic use that is not commensurate with what is actually claimed.

Further, the claimed invention is not supported by a substantial utility, because no substantial utility has been established for the claimed subject matter. While the model may be able to generate testable hypotheses, be used for diagnostics, and identify drug targets, further research would be required to confirm a “real world” context of use. For example, Applicants mention that on page 28, paragraphs 3 and 4, the identified altered elements are potential drug targets and that a drug that alters properties of the identified element should cause the disease cell to become normal. However, such assertions would clearly require further research to confirm that such elements were indeed drug targets. Further research would also be required to confirm the identification of an effective drug. Using a model without a specific and substantial utility does not define a “real world” context of use.

As set forth in *Brenner v. Manson* (148 USPQ 689 (1966)) and *In re Ziegler* (26 USPQ2d 1600), the “usefulness” of an invention must be immediately apparent to those familiar with the technological field of the invention. As further research would be required to “use” the model

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and program encoded in the claimed article, the apparent result of the model and program is not “immediately useful” and lacks utility

Due to a lack of either an art recognized or alleged well established utility, the instant invention has been rejected due to also lacking the required combination of a specific, -substantial, and credible utility. Although it may be credible that the claimed invention has the above mentioned utilities, the lack of a specific and substantial utility, as explained above, sufficiently supports this rejection.

LACK OF ENABLEMENT

Claims 18-22, 27, 30, 32-33, 96-98, 100, and 102-107 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either an asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 18-22, 27, 30, 32-33, 96-98, 100, and 102-107 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 18, 20, and 32 recite limitations “that express” (claim 18, line 7), “being expressed” (claim 18, line 9 and claim 32, line 4), “to process” (claim 18, line 10), “is typed” (claim 18, line 14), “are organized” (claim 18, line 15), “is matched” (claim 18, line 16), “expresses” (claim 20, line 1), “express” (claim 32, line 2), and “to infer” (claim 32, line 5) which lack clarity. It is unclear if these limitations are intended to be method steps in the claimed composition. It is unclear how these method step limitations limit the model. Clarification of this issue via clearer claim wording is requested. Claims 19-21, 22, 27, 30, and 33 are also rejected due to their dependency from claims 18 and 32.

Claim 18 (penultimate line) recites the phrase “is matched by” which lacks clarity. It is unclear what this phrase is intended to mean. It is unclear if this matching is occurring during a substitution or some other time. Clarification of this issue via clearer claim wording is requested. Claims 19-22, 27, and 30 are also rejected due to their dependency from claim 18.

Claims 32, 96, and 105 recite the phrase “based on” which is vague and indefinite. It is unclear what parameters and to what degree these parameters must be met to be considered to be “based on.” Clarification of this issue via clearer claim wording is requested. Claims 33, 97-98, 100, and 102-104 are also rejected due to their dependency from claims 32, 96, and 105.

Claims 96, 105, and 106 recite the limitation “the processor” in line 2. There is insufficient antecedent basis for this limitation in the claim as there is no previous mention of a processor. Correction of this issue is suggested by amending the word “the” to the word “a”.

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Claims 97-98, 100, 102-104, and 107 are also rejected due to their dependency from claims 96, 105, and 106.

Claim 106 contains several issues which lack clarity. It is unclear what the connection is between values reflecting the abundance of an element in the first state and the iterative substitution step. It is unclear what meant by the phrase "terminal state". It is unclear what the "terminal state" reflects with regard to the abundance values. Clarification of this issue via clearer claim wording is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 18-22, 27, 30, 32-33, 96-98, 100, and 102-107 are rejected under 35 U.S.C. 102(b) as being anticipated by Thalhammer-Reyero (US 5,980,096).

Thalhammer-Reyero discloses a hardware and software environments for their systems, graphical interfaces, and methods for graphic information storage and retrieval, visual modeling, and dynamic simulation of complex biochemical systems that can encode modeling and simulation knowledge in sets of icons connected in schematics (col. 4, lines 59-67; col. 8, lines 56-67; and col. 18, lines 13-19) as well as processor and program means (claim 72) which

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represents an article comprising machine-readable media having encoded thereon a model of a biological system (as stated in the preamble of instant claims 18 and 32) and software configured to cause a processor to run a method (as stated in instant claims 96 and 106). Thalhammer-Reyero discloses representing characteristics of biochemical and cellular entities in the form of symbols as well as the parallel and serial sets of processes in which they interact (col. 5, line 63 to col. 6, line 6 and col. 6, lines 50-54) and intracellular signaling pathways and lists of cell types containing certain molecules (col. 10, lines 46-50 and col. 54, lines 6-9) which represents symbols representing one or more biological elements of a biological system in an initial hypothetical state (as stated in instant claim 18) and first and second sets of symbols from cells (as stated in instant claim 32). The list of cells containing certain molecules (col. 10, lines 46-50) also represents one or more symbols in a first set being in a second set, as stated in instant claim 33. Thalhammer-Reyero discloses that these entities represented by icons may participate in synthesis, degradation, modifications, interactions and translocation processes and can change dynamically at run time (col. 6, lines 30-39). Thalhammer-Reyero discloses inference engines that search for and execute relevant rules and methods that comprise rules and procedures that are object-oriented and applied to the bioObjects as well as creating and modifying models as needed based on experimentation based on these rules and interactions involving alternatives (abstract, col. 3, lines 59-62; col. 6, lines 39-45; and col. 10, lines 1-24) which represents substituting symbols, rules representing interactions between biological elements, and an inference engine to process rules for initial and alternative (modified) states, as stated in instant claims 18 and 32. Thalhammer-Reyero discloses describing characteristics of objects as symbols with text, values, variables, or other attributes (col. 6, lines 50-62) which represents the symbols

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being typed, as stated in instant claims 18, 102, and 107. Thalhammer-Reyero discloses objects within classes as well as chemical processes and their participants arranged in hierarchies (col. 5, lines 1-16 and col. 6, lines 63-67) which represents an organization of hierarchical classes, as stated in instant claims 18 and 103. Thalhammer-Reyero discloses class hierarchy and performing methods attached to an object's class (col. 4, lines 1-11) which represents a symbol (object) being matched by another symbol (object) that is a member of the hierarchical class, as stated in instant claims 18 and 104. Thalhammer-Reyero discloses units of all variables in all bioPools connected to the same bioprocess have to be appropriately matched (col. 58, lines 58-62) which represents a symbol being matched to another symbol that is a member of the hierarchical class, as stated in instant claims 18 and 104. Thalhammer-Reyero discloses mathematical models, manipulating data via operations, using methods associated with component icons and interconnecting each pool to several processes, using functions and graphical interfaces associated with each icon (abstract and col. 15, lines 32-34), and modes of operation and display including rule processing and relationships as well as formulas and functions (col. 37, lines 43-51) which represent operators expressing a relationship between biological elements and conforming to associative and commutative properties, as stated in instant claims 19 and 97. Thalhammer-Reyero discloses concurrently monitoring thousands of variables (col. 4, lines 23 and 39-40; col. 18, lines 35-37) and executing rules and procedures to implement different strategies concurrently over time supporting symbolic expression (col. 19, lines 18-25) which represents rules expressing concurrent state transitions, as stated in instant claims 20 and 98. Thalhammer-Reyero discloses iterating the process (col. 9, lines 57-59) which represents that some of the rules are not terminating, as stated in instant claim 21. Thalhammer-

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Reyero discloses programming the models into networks of interacting pathways including feedback and forward loops (col. 6, lines 20-24), as stated in instant claims 22 and 100.

Thalhammer-Reyero discloses a function involving an “if...then” statement (col. 52, lines 1-7) which represents a rule that is conditional, as stated in instant claim 27. Thalhammer-Reyero discloses symbols representing entities participating in pharmacological reactions (col. 5, line 66 to col. 6, line 6 and col. 6, line 54) and pharmacological or other experimental molecules added to the system from an external environment (col. 59, lines 4-6) which represents a symbol that represents an exogenous agent, as stated in instant claim 30. Thalhammer-Reyero discloses an inference engine that receives input from a user (col. 19, lines 28-34), iterating the process (col. 9, lines 57-59), inference engines that search for and execute relevant rules and methods that comprise rules and procedures that are object-oriented and applied to the bioObjects as well as creating and modifying models as needed based on experimentation based on these rules and interactions involving alternatives (abstract, col. 3, lines 59-62; col. 6, lines 39-45; and col. 10, lines 1-24; and Tables 54-55) which represents substituting symbols, rules representing interactions between biological elements, and an inference engine to process rules for initial and alternative (modified) states, as stated in instant claim 96, 105, and 106. Thalhammer-Reyero discloses the use of a second set of variables (col. 60, lines 23-29) which represents a second set for a second state of a biological system, as stated in instant claim 105. Thalhammer-Reyero discloses comparing two lists of bioReservoirs and bioEntities (symbol sets), loops over all entities from a bioReservoirs and scans connections to certain classes (col. 96, lines 45-51; col. 97, lines 40-65; and col. 100, lines 23-57) which represents comparing a second set to one of the alternate states (as mentioned above), as stated in instant claim 105. Thalhammer-Reyero

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discloses scanning the density value of the bioReservoir according to a symbolic value of the abundance attribute in a normal state and then the inference engine scans values of other sources in alternative states to compare to a threshold parameter (col. 107, lines 7-67; col. 112, lines 30-33; Tables 56 and 58; Figures 27-28) as well as initial conditions of basal quantity such that scaled-value set of variables are constrained not to be less than 0 and only activating and deactivating certain groups (col. 113, lines 13-35) which represents maintaining value if it exceeds the threshold parameter, as stated in instant claim 106.

Thus, Thalhammer-Reyero anticipates the instant invention.

Applicants' arguments regarding the previous prior art are moot as a new reference is used for prior art purposes.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform to the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (571) 272-0549.

September 13, 2005

MARJORIE A. MORAN
PRIMARY EXAMINER

Marjorie A. Moran
9/19/05